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New England Medical Corporation

2274 Albany Post Road, Walden, NY 12586
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510(K) Summary

Submitted By/Contact: Steven Fodor
Title: President
Company: New England Medical Corporation
Address: 2274 Albany Post Road
Walden, NY 12586
Phone: (845) 778-4200
Fax: (845) 778-4199
Submission date: Jul. 2, 2000

DEVICE PROPRIETARY NAME: TruCone Rotational Cone Biopsy Instrument

DEVICE COMMON NAME: Electrosurgical Active Electrode

DEVICE CLASSIFICATION NAME: Electrode, Electrosurgical

PREDICATE DEVICE: Fisher Cone Biopsy Excisor, Apple Medical

PRODUCT DESCRIPTION

The TruCone Rotational Cone Biopsy Instrument is an electrosurgical active electrode for the excision of cone shaped samples of cervical tissue. The three small prongs stabilizes the tissue being excised while a freely rotating middle core and grooved "handle" on the shaft contributes to the operators control rotating the shaft.

Constructed from a stainless steels shaft, Acrylic Molding Compound, polyoleofin shaft insulation, and a Tungsten wire cutting surface, the device is sold STERILE for SINGLE USE.
The TruCone is available in various sizes:

TruCone Sizes

No.		DIA	High
231812	**Small**	18mm	12mm
231815	**Small – Extended**	18mm	15mm
231818	**Small – Deep**	18mm	18mm
232412	**Medium**	24mm	12mm
232415	**Medium – Extended**	24mm	15mm
232418	**Medium – Deep**	24mm	18mm
233012	**Large**	30mm	12mm
233015	**Large – Extended**	30mm	15mm
233018	**Large - Deep**	30mm	18mm

The TruCone is individually packaged in a heat sealed chevron Tyvek pouch, 5 packages per box, which is the selling unit.

STATEMENT OF INDICATION FOR USE

- Cervical Conizations
- Large Loop Excision of the Transformation Zone (LLETZ) in the diagnosis and treatment of some Cervical Intraephitelial Neoplasias (CIN and Dysplasias.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 1 2001

Mr. Steven Fodor
President
New England Medical Corporation
2274 Albany Post Road
WALDEN NEW YORK 12586

Re: K002042
TruCone Rotational Cone Biopsy Instrument
Dated: October 30, 2000
Received: November 3, 2000
Regulatory Class: II
21 CFR §884.4120/Procode: 85 HGI

Dear Mr. Fodor:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

TRUCONE ROTATIONAL CONE BIOPSY INSTRUMENT
ADDENDUM

STATEMENT OF INDICATION FOR USE

As an addendum, this replaces the original submission for the indicated uses.

The TruCone Rotational Cone Biopsy Device is indicated for:

Cervical Conization

Large Loop Excision of the Transformation Zone (LLETZ) in the diagnosis and treatment of some cervical intraepithelial neoplasia (CIN) and dysplasias.

Prescription Use ✓
(Per 21 CFR 801.109)

David A. Bergman
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K002042